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Picha et al.

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[45] **Date of Patent: Feb. 1, 2000**

[54] **LOW PROFILE BALLOON FEEDING DEVICE**

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[73] Assignee: **Applied Medical Technology, Inc.**, Cleveland, Ohio

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Related U.S. Application Data

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[51] **Int. Cl.**[7] **A61M 5/32**

[52] **U.S. Cl.** **604/175**; 604/96; 604/256

[58] **Field of Search** 604/96–102, 256, 604/246, 247, 174, 175; 600/29–32

[56] **References Cited**

U.S. PATENT DOCUMENTS

5,125,897	6/1992	Quinn et al.	604/99
5,342,321	8/1994	Potter	604/174
5,411,491	5/1995	Goldhardt et al.	604/247
5,413,565	5/1995	Michels et al.	604/247
5,556,385	9/1996	Anderson	604/174
5,718,691	2/1998	Russo	604/247

Primary Examiner—Wynn Wood Coggins
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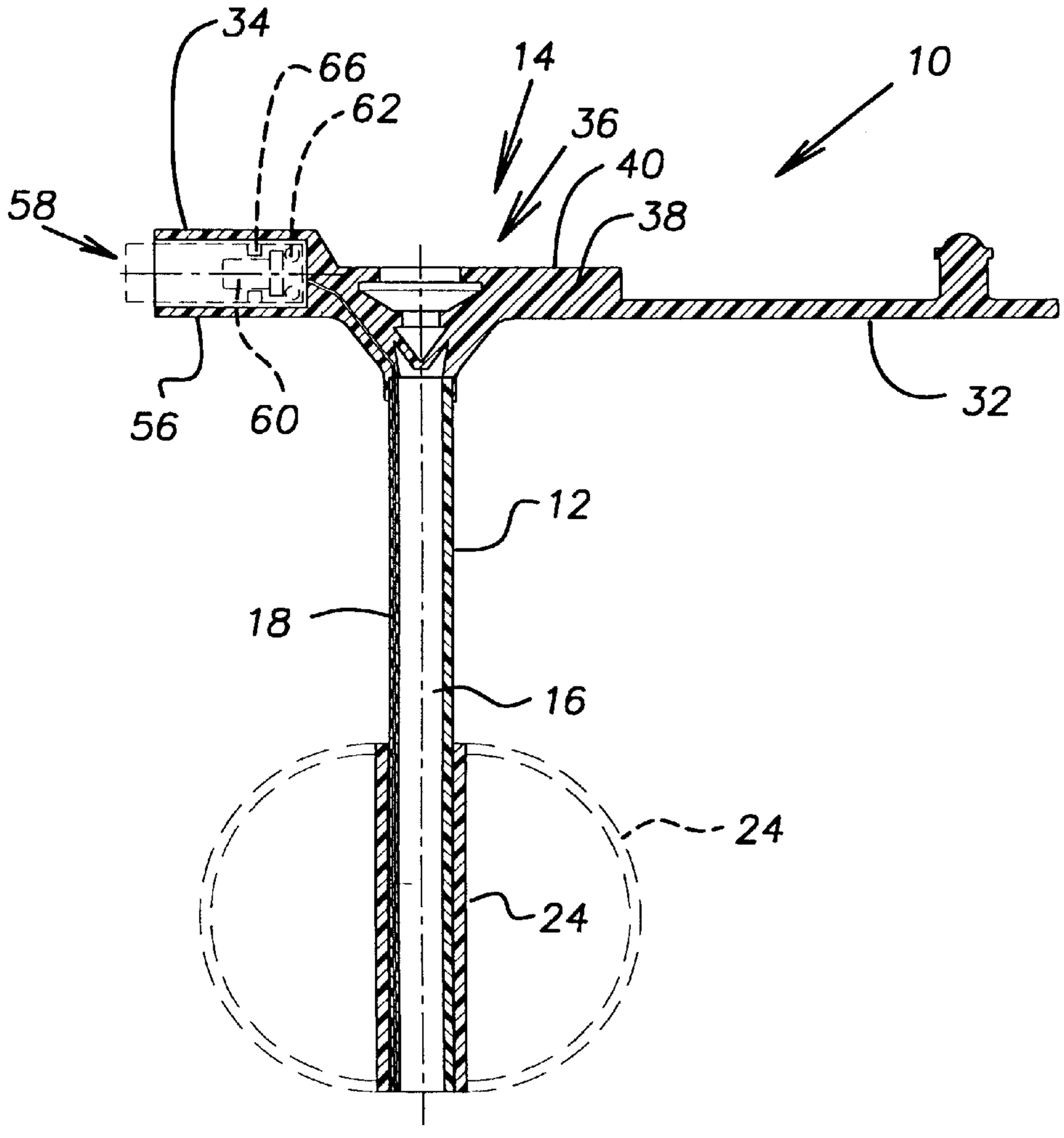
[57] **ABSTRACT**

A low profile gastrostomy feeding device having a bolster portion, a balloon member, and tubular member extending between the bolster portion and the balloon member. The bolster portion includes an anti-reflux valve, a closure member, an inflation valve housing, and a cap retainer portion. An inflation lumen and a feeding lumen are provided by the tubular member. The inflation lumen curves as it passes through the bolster portion from the tubular member to the inflation housing.

11 Claims, 4 Drawing Sheets



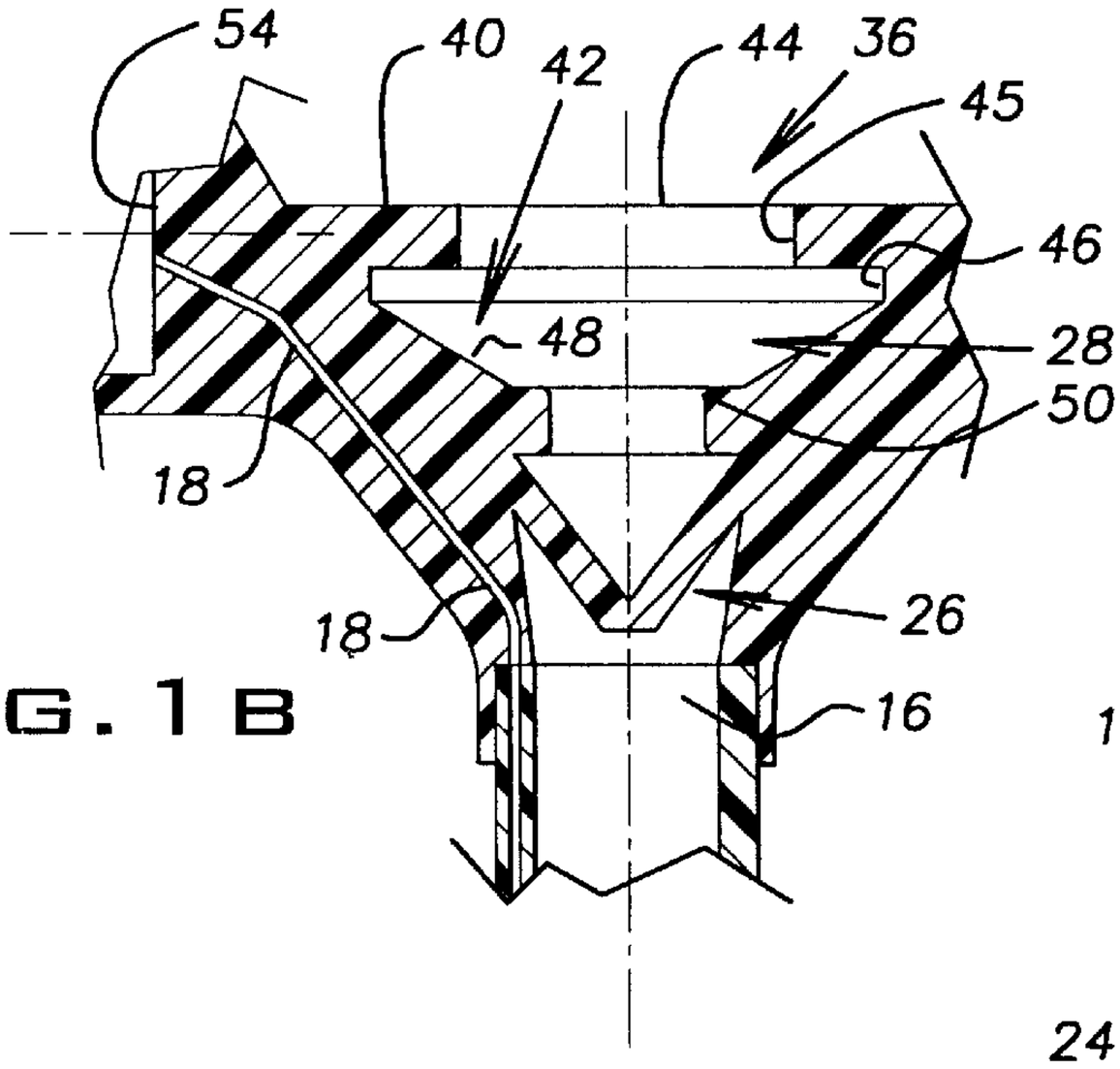


FIG. 1B

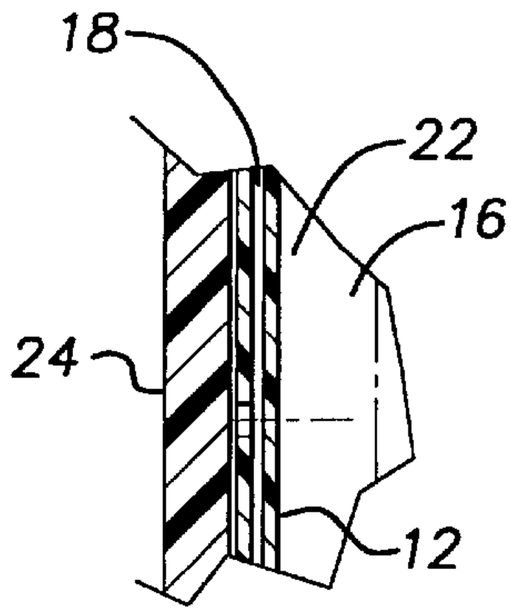


FIG. 1C

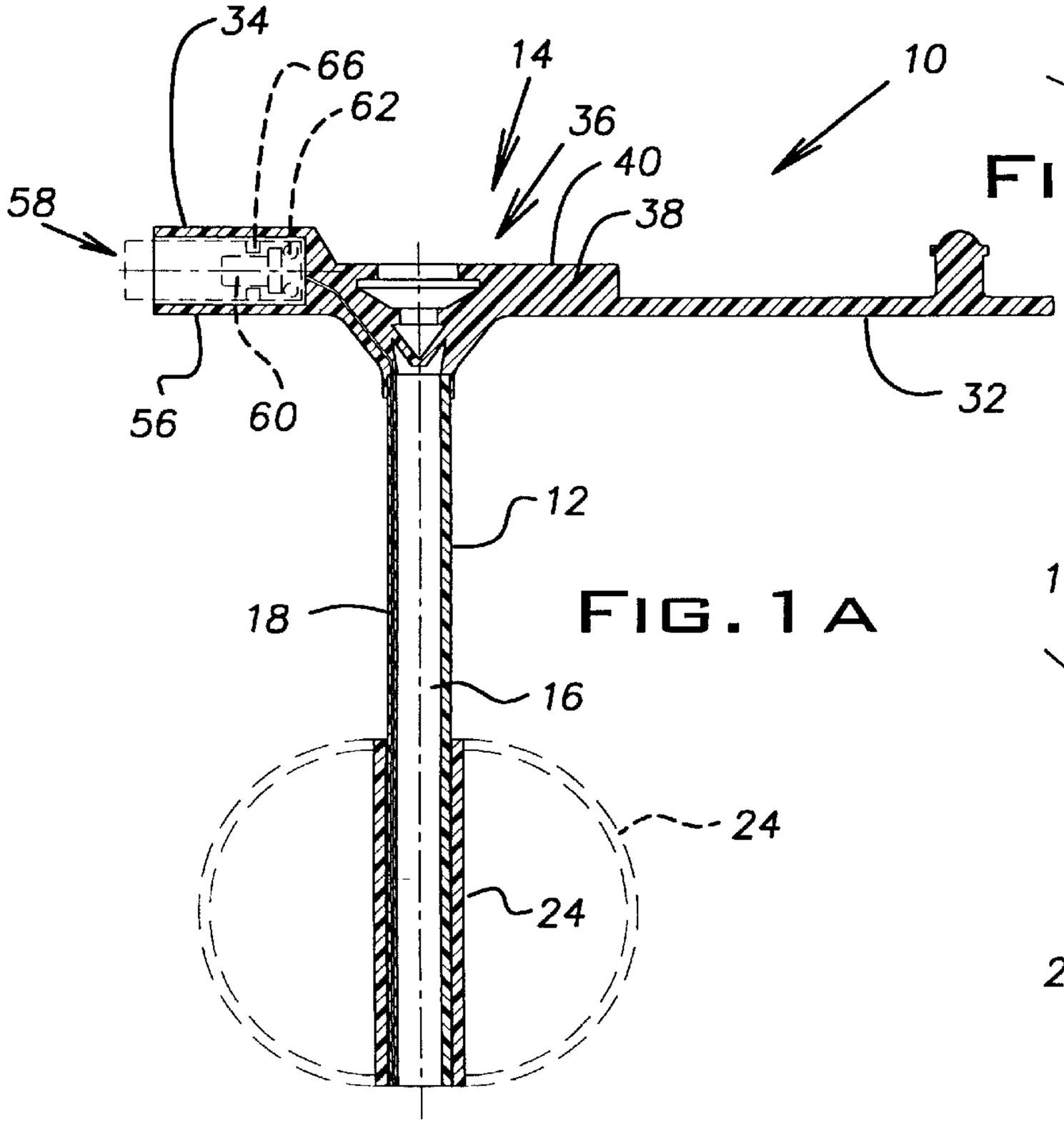


FIG. 1A

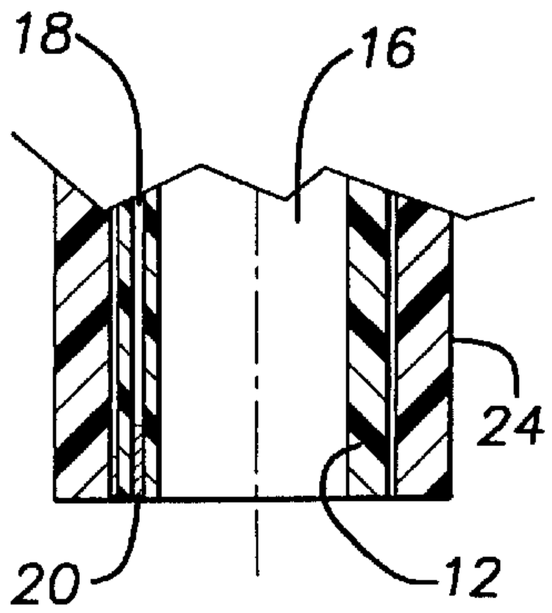


FIG. 1D

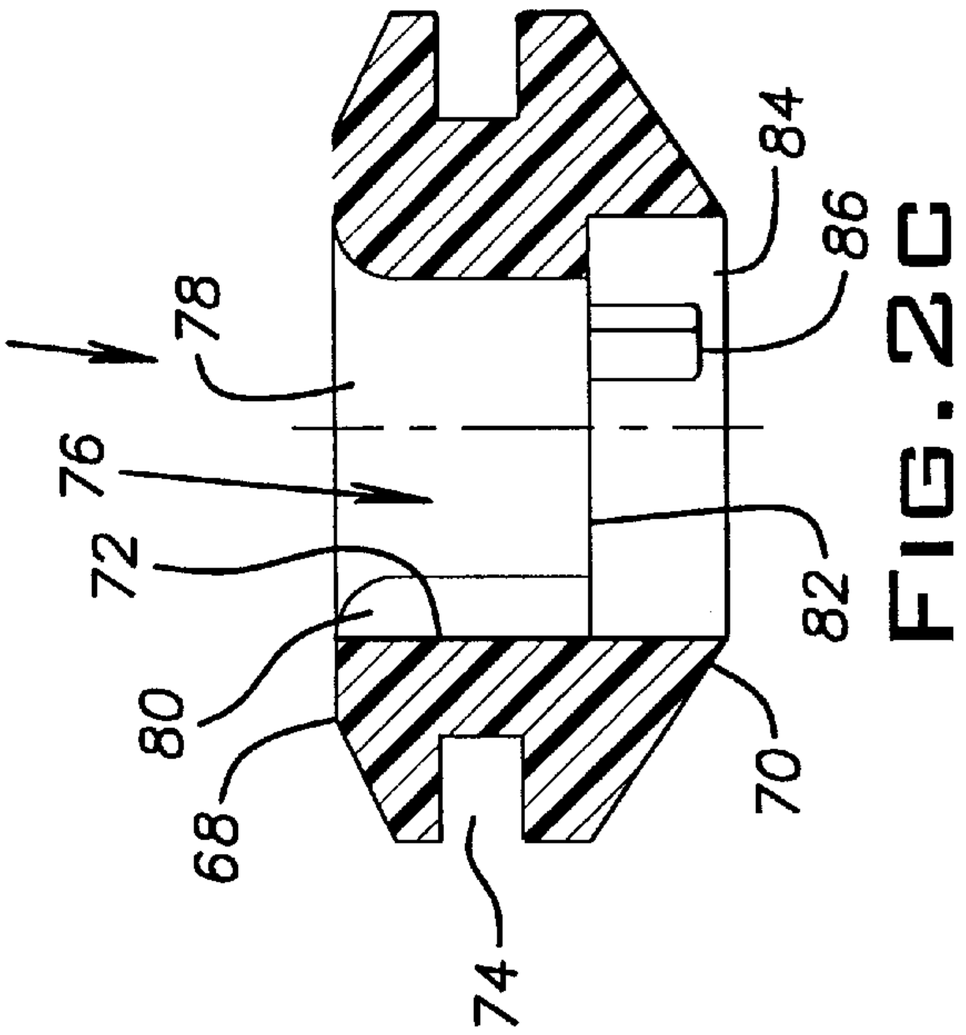


FIG. 2C

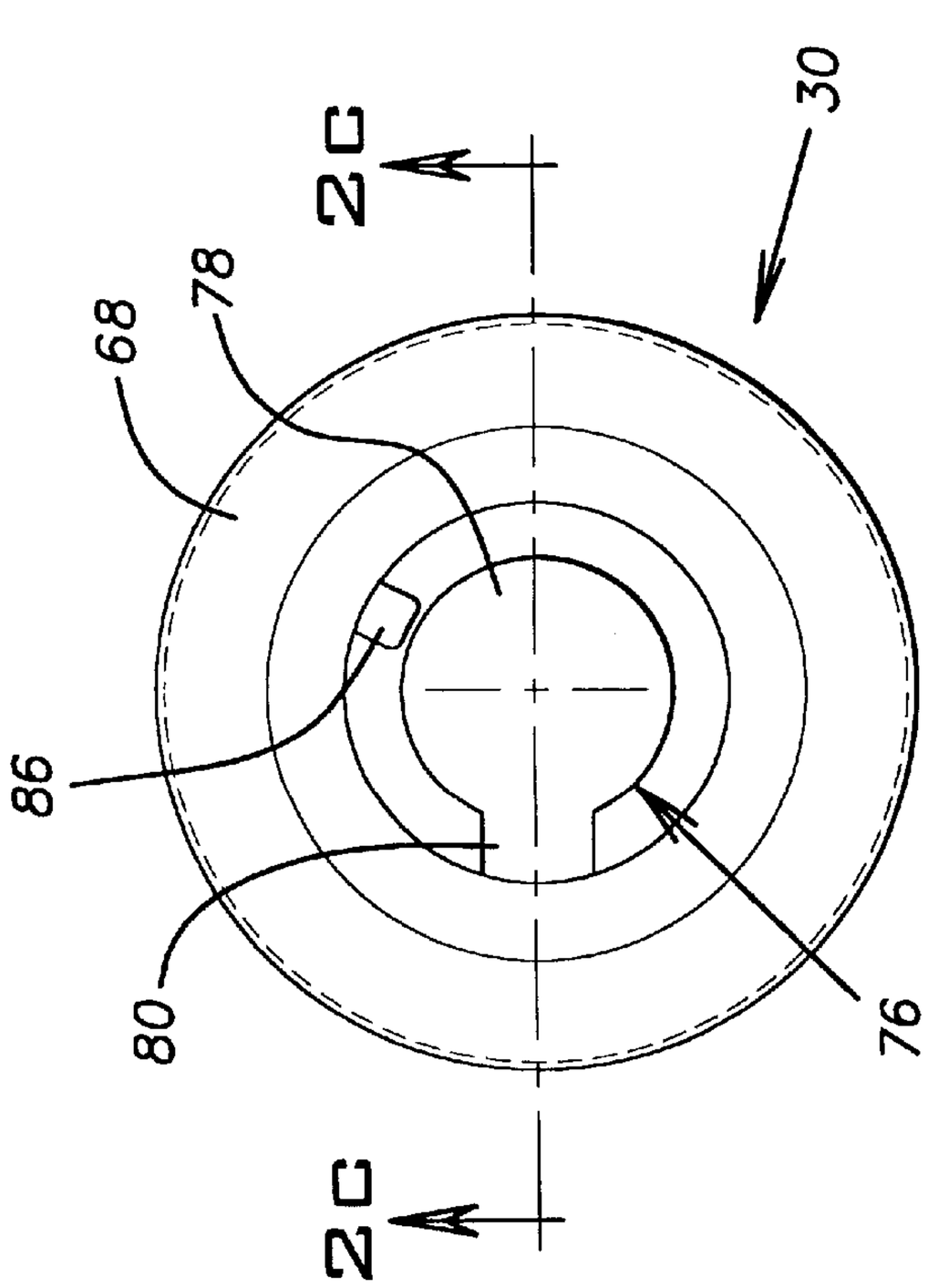


FIG. 2B

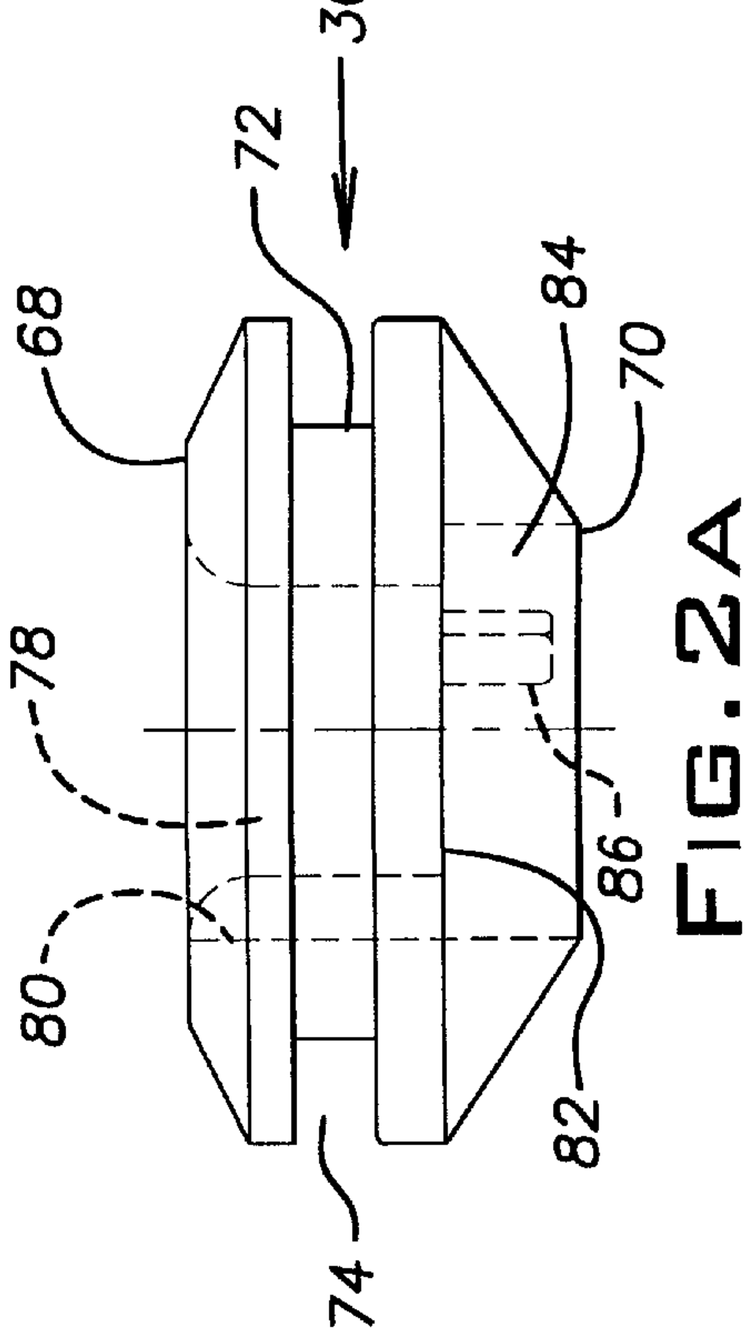


FIG. 2A

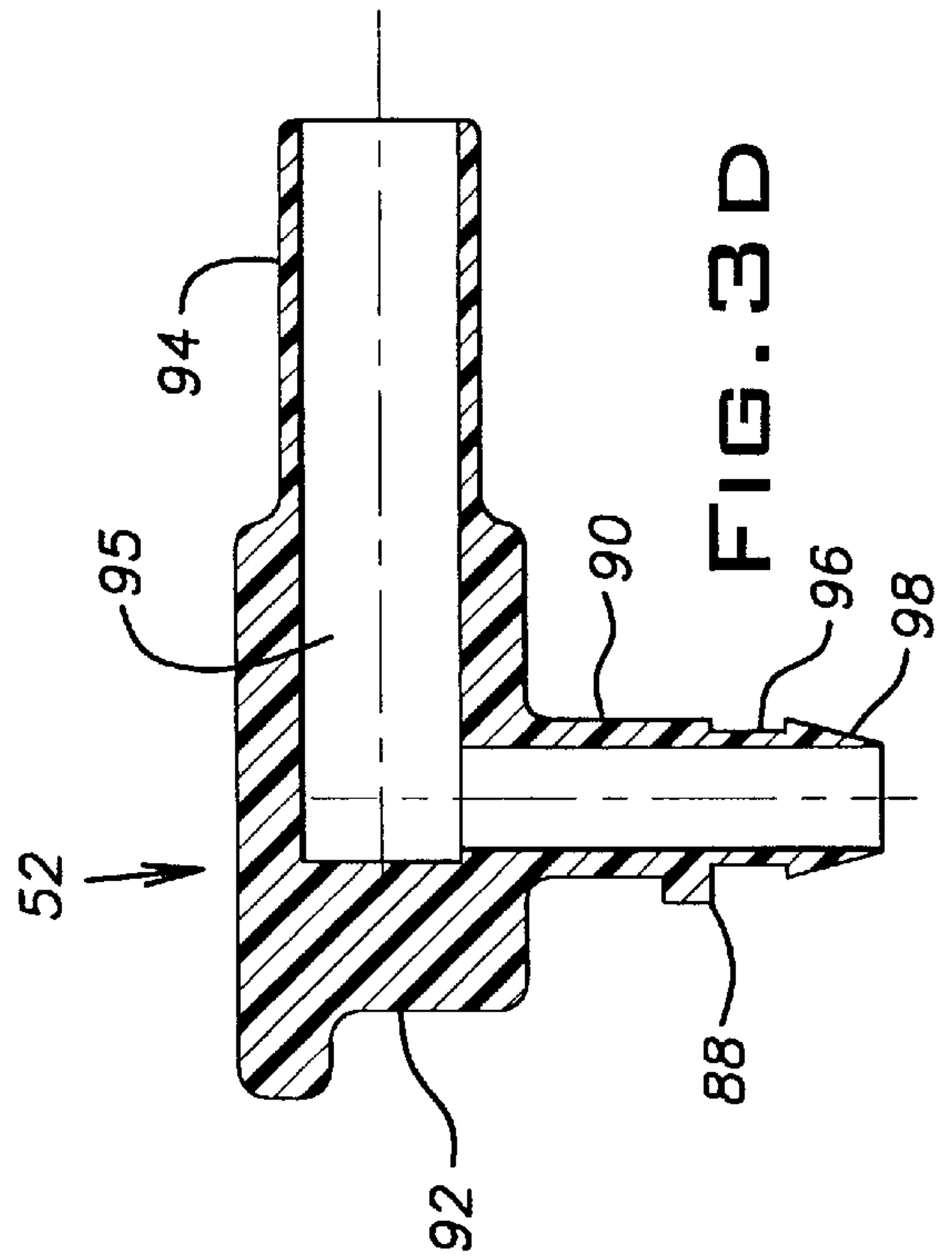


FIG. 3D

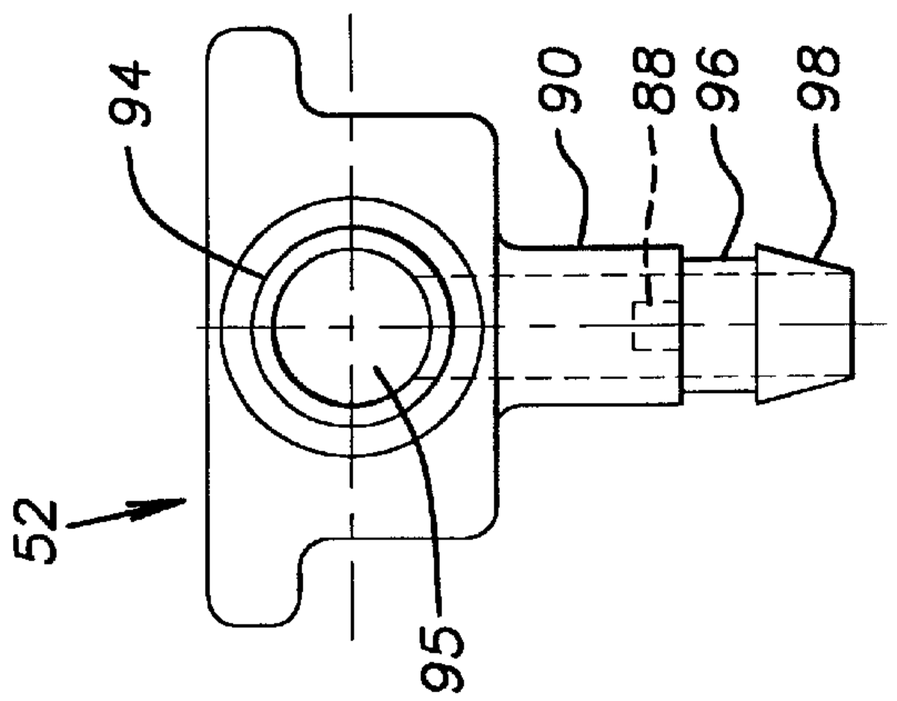


FIG. 3B

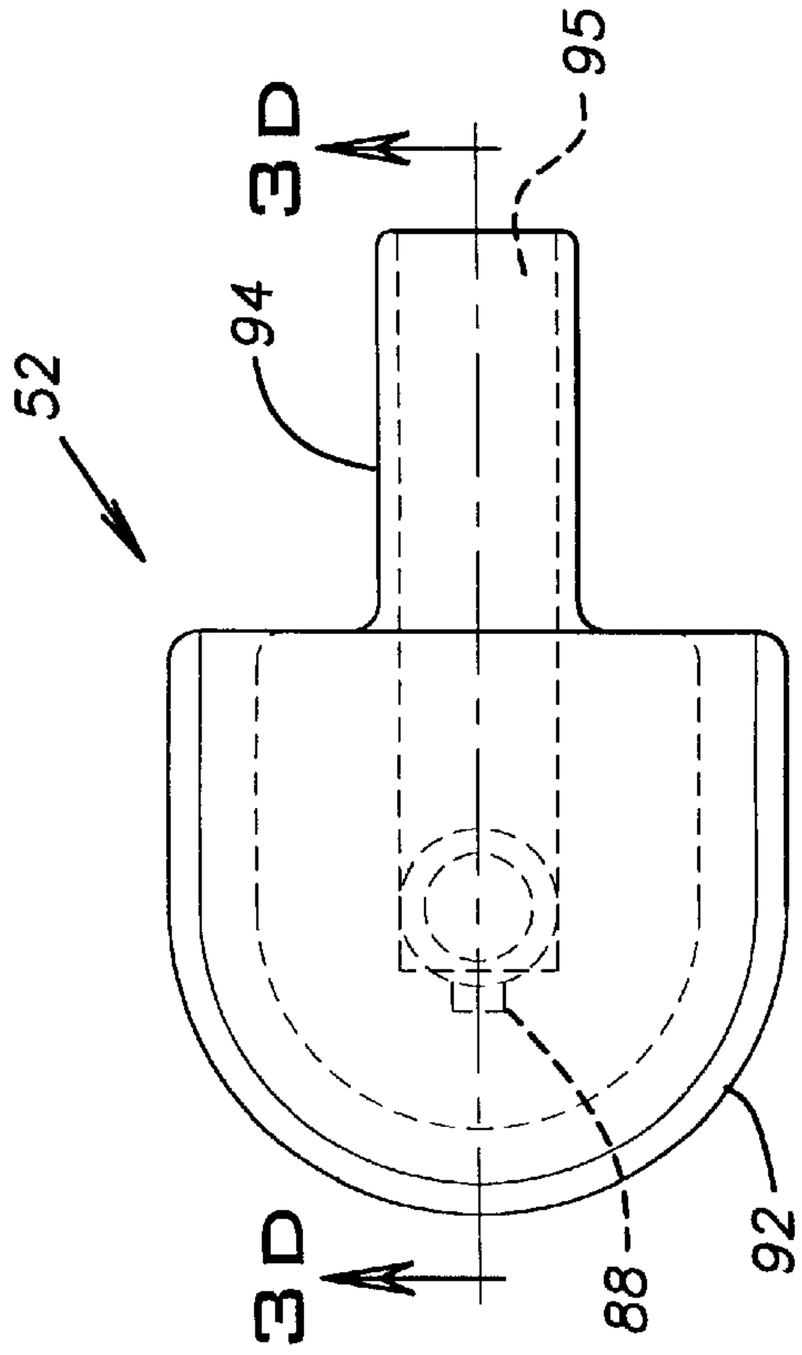


FIG. 3C

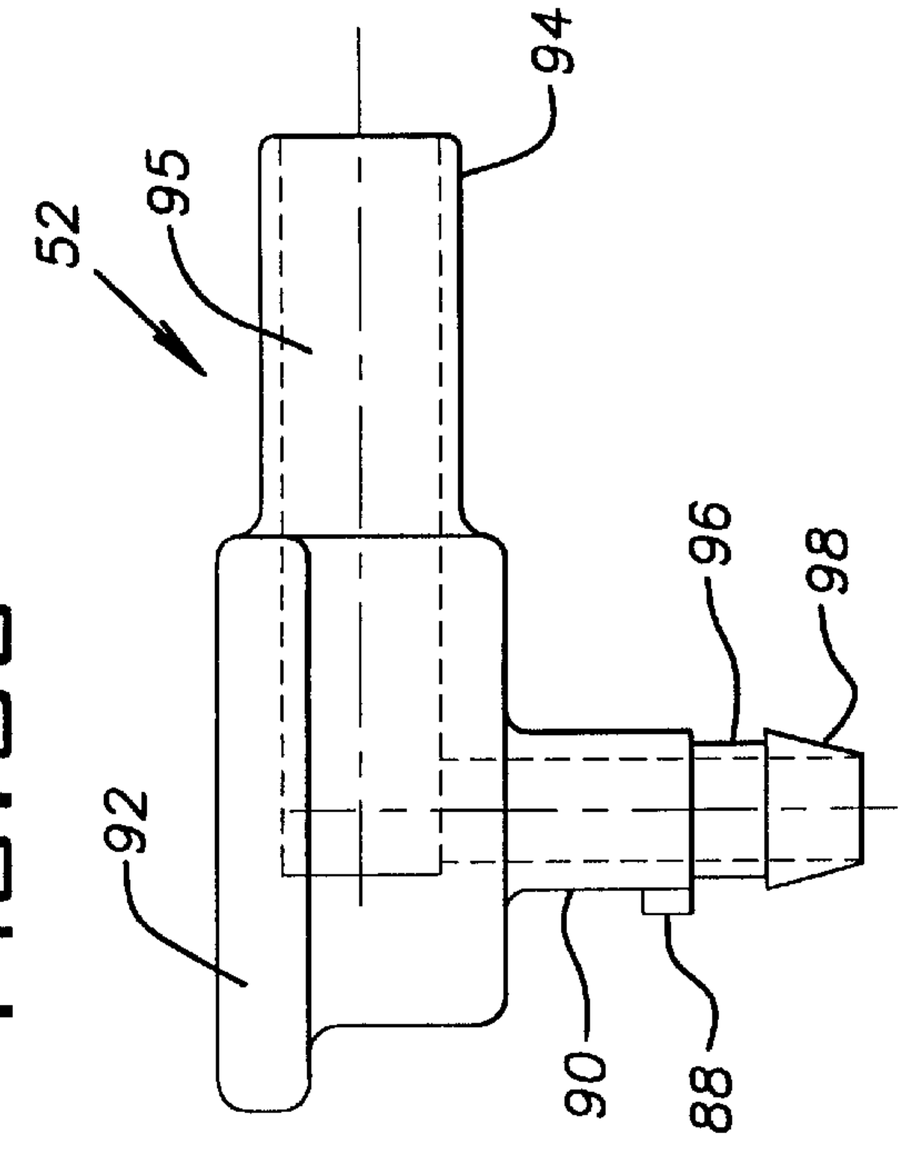


FIG. 3A

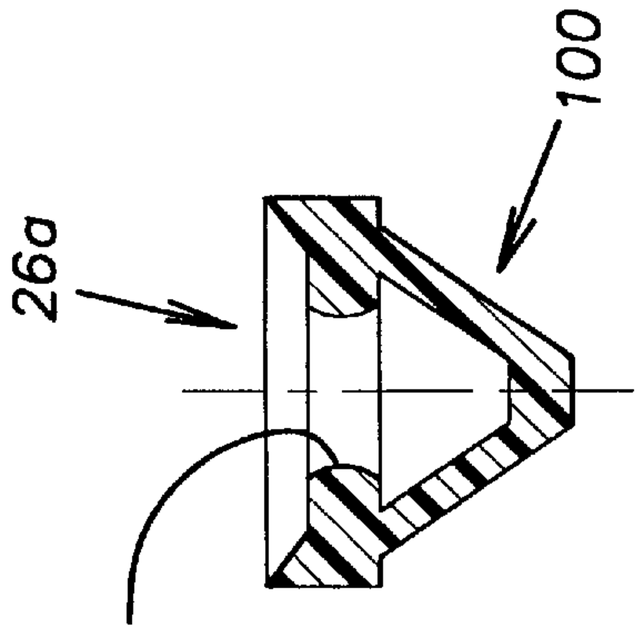


FIG. 4C

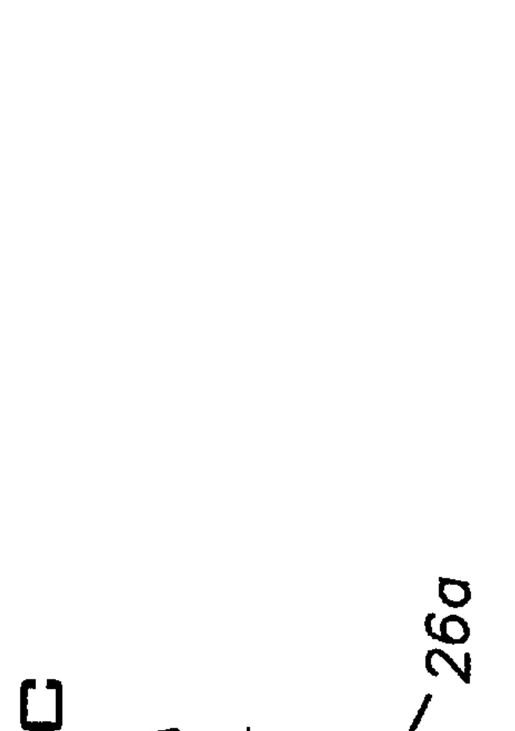


FIG. 4B

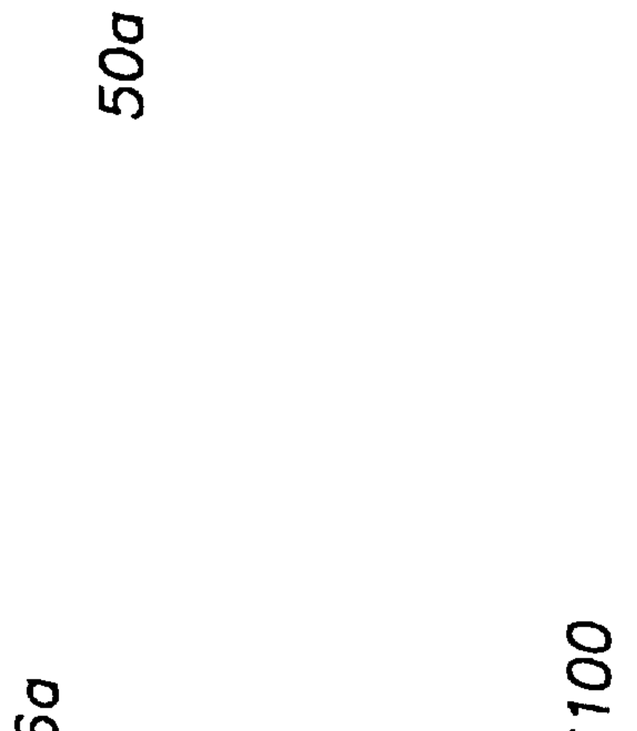


FIG. 4A

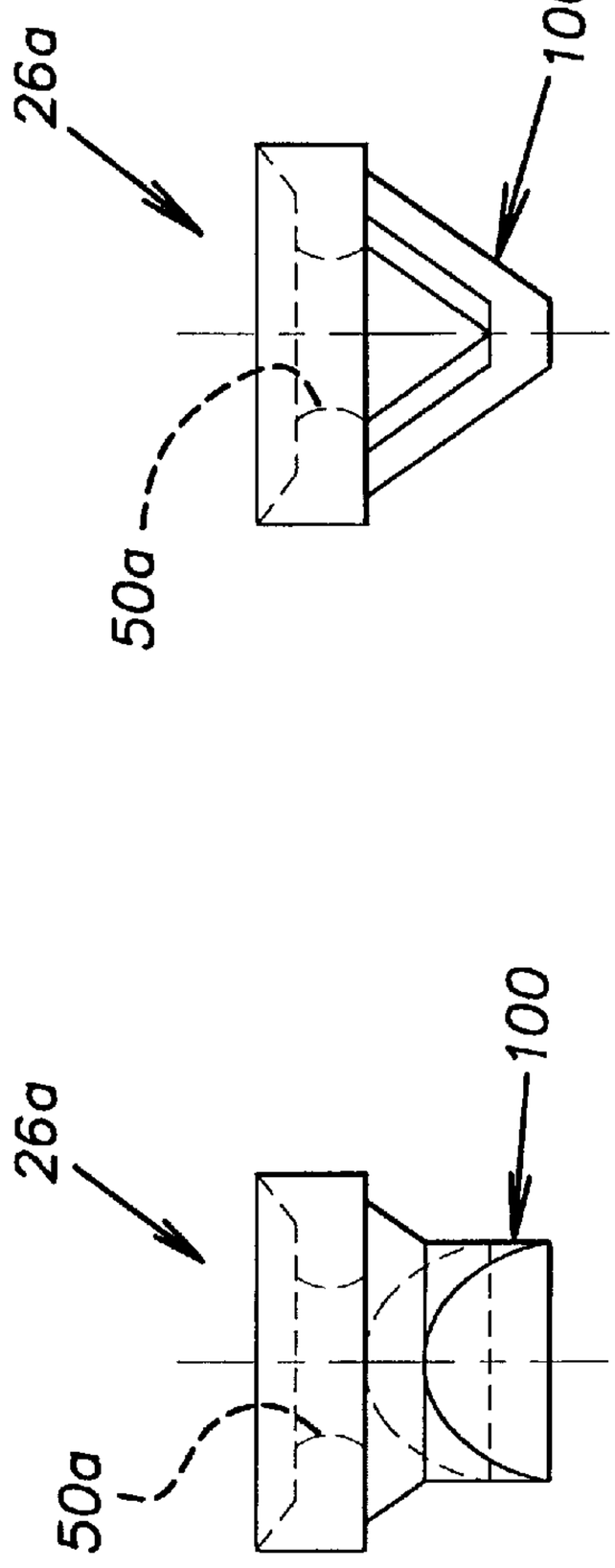


FIG. 4D

LOW PROFILE BALLOON FEEDING DEVICE

CROSS REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of U.S. provisional application Ser. No. 60/018,374, filed May 17, 1996.

BACKGROUND OF THE INVENTION

The present invention is directed toward gastrostomy feeding appliances or devices and, more particularly, to gastrostomy devices, methods for manufacturing gastrostomy devices, and methods for securing gastrostomy devices to a patient.

Over the years, several different designs for gastrostomy feeding devices have been proposed. Each of these designs has an internal bolster, an external bolster, and a feeding conduit that extends from the external bolster toward or through the internal bolster. A valve is typically provided to prevent reflux of gastric fluid through the feeding conduit. The internal bolster prevents the feeding conduit from being withdrawn from the patient's stoma, and the external bolster provides means for connecting the feeding device with a food supply tube.

Generally, these prior art feeding device designs may be separated into two basic categories: those with fixed, non-expandable internal bolsters, and those with expandable or inflatable internal bolsters. With regard to the latter category, several problems have been encountered.

The prior art expanding bolster designs have not satisfied the conflicting requirements of such feeding devices. The inflatable bolster must be capable of selected inflation/deflation and must be inflated and deflated from an exterior of the patient's body. The exterior bolster should not protrude too far from the patient's body, both for the patient's comfort and to prevent the bolster from becoming snagged on the patient's clothes or other items. The air passageway or lumen connecting the interior balloon to the exterior, must not significantly increase the diameter or material thickness of the tubular member extending between the interior and exterior bolsters. The air passageway must not interfere with the food supply tube connecting means and must not weaken the overall device design. Finally, the internal and external bolsters must not interfere with placement or removal of the device.

Due to these competing interests, there exists a need in the art for a low profile balloon feeding or gastrostomy device which balances these conflicting requirements and which provides a readily usable and satisfactory design.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide a low profile balloon feeding or gastrostomy device which is easily manufactured, installed and used. It is a further object of the present invention to provide such a feeding device wherein an air lumen is provided by a tubular member, and wherein the air lumen does not significantly increase the diameter of the tubular member.

In accordance with the present invention, a feeding device includes an elongated tubular member and an exterior bolster portion. The tubular member includes a feeding lumen and an inflation lumen, each of which extend longitudinally the length of the tubular member. The inflation lumen is in fluid communication with a balloon member that defines an internal bolster.

In further accordance with the present invention, the inflation passage and the feeding passage extend through the exterior bolster portion. At the union of the bolster portion and the tubular member, the feeding passage is closed by an anti-reflux or one-way check valve, and immediately above the valve, the feeding lumen defines a receptacle for a locking cap member.

In further accordance with the present invention, the external bolster includes the valve, a closure member, an inflation valve housing, and a cap retainer portion, at least some of which are provided by a continuous wall portion. The valve may be integrally formed with the bolster portion.

In further accordance with the present invention, the inflation passage curves as it passes through the bolster portion between the inflation valve housing and the tubular member. Curving of the inflation passage cooperates with the locking cap member receptacle to provide a generally constant thickness of material between the passage and the receptacle.

The inflation valve housing sealingly receives an inflation valve by means of which the balloon may be selectively inflated or deflated.

BRIEF DESCRIPTION OF THE DRAWINGS

These and further features of the present invention will be apparent with reference to the following description and drawings, wherein:

FIG. **1***a* is a front, cross-sectional view of a low profile balloon feeding device according to the present invention;

FIG. **1***b* is an enlarged sectional view of an anti-reflux valve of the feeding device shown in FIG. **1***a;*

FIG. **1***c* is an enlarged sectional view of an intermediate portion of a tubular member of the feeding device shown in FIG. **1***a;*

FIG. **1***d* is an enlarged sectional view of a lower portion of the tubular member of the feeding device shown in FIG. **1***a;*

FIG. **2***a* is a front elevational view of a locking cap member used with the feeding device according to the present invention;

FIG. **2***b* is a top plan view of the locking cap shown in FIG. **2***a;*

FIG. **2***c* is a cross sectional view of the locking cap shown in FIGS. **2***a* and **2***b*, as seen along line **2***c*–**3***c* of FIG. **2***b;*

FIG. **3***a* is a front elevational view of a feeding adapter used in conjunction with the feeding device according to the present invention;

FIG. **3***b* is an end elevational view of the feeding adapter shown in FIG. **3***a;*

FIG. **3***c* is a top plan view of the feeding adapter shown in FIGS. **3***a* and **3***b;*

FIG. **3***d* is a cross sectional view of the feeding adapter as seen along line III—III in FIG. **3***c;*

FIG. **4***a* is a front elevational view of an alternative anti-reflux valve used in conjunction with a second embodiment of the present invention;

FIG. **4***b* is a top plan view of the alternative anti-reflux valve shown in FIG. **4***a;*

FIG. **4***c* is a cross-sectional view of the alternative anti-reflux valve as seen along line **4***c*—**4***c* of FIG. **4***b;*

FIG. **4***d* is a side elevational view of the alternative anti-reflux valve according to the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

With reference to FIGS. **1***a*–**1***d,* a low profile balloon feeding device **10** according to the present invention is

illustrated. The feeding device **10** includes an elongated tubular member **12** and a bolster portion **14**, as illustrated.

The tubular member **12** includes a feeding lumen or passage **16** and an inflation lumen or passage **18**. Preferably, the feeding and inflation passages **16**, **18** extend longitudinally the length of the tubular member **12**. The feeding passage **16** is generally coaxial with an axis of the tubular member **12**. The inflation passage **18** is parallel to, but offset laterally from, the feeding passage **16**, as illustrated.

Preferably, a lower end of the inflation lumen **18** is blocked by a plug **20** (FIG. **1***d*). A lateral or radially opening bore **22** (FIG. **1***c*) through the tubular member **12** and into the inflation passage **18** is provided to permit fluid to flow between the inflation passage **18** and a balloon member **24** which radially surrounds the tubular member **12**. The balloon member **24** is cylindrical or tubular in shape when deflated or at-rest, and the bottom and top portions of the balloon member are sealed to the tubular member **12**, as is well known in the art. The balloon member is inflated (deflated) by introduction (removal) of air, saline, or other fluid into the balloon member **24** via the inflation passage **18** and the bore **22**, as is well known in the art. The balloon member in an inflated state is shown in dashed lines in FIG. **1***a*.

The inflation passage **18** and feeding passage **16** extend through the bolster portion **14**. Generally, at the juncture or union of the bolster portion **14** and the tubular member **12**, as shown in FIG. **2**, the feeding passage **16** is closed by an anti-reflux valve **26**. Relatively above the anti-reflux valve **26**, the feeding lumen **16** defines a receptacle **28** for a locking cap member **30** (FIGS. **2***a*–**2***c*), as will be described more fully hereinafter.

The bolster portion **14** includes, in addition to the anti-reflux valve **26**, a closure member **32**, an inflation valve housing **34**, and a cap retainer portion **36**. The cap retainer portion **36**, inflation valve housing **34**, and closure member **32** are at least partially provided by a continuous wall member **38**, as illustrated.

The cap retainer portion **36** provides the receptacle **28** for the locking cap member **30**. The retainer portion includes the wall member **38** which has a generally planar outer surface **40**, and a radial wall **42** having an inner surface which defines a portion of the feeding passage and generally conforms to the peripheral shape of the locking cap member **30**, to be described hereafter. The outer surface is penetrated by an opening **44** for the feeding passage **16**. An annular rib **45** surrounds the opening **44** and serves to retain the cap member **30** within the receptacle **28**. The feeding passage opening **44** at the outer surface **40** has a first, relatively larger, diameter as compared to the diameter of the feeding passage **16** within the tubular member **12**.

With reference to FIG. **1***b*, relatively below the wall member outer surface **40**, the radial wall **42** defines receptacle **28** which receives and retains a portion of the locking cap member **30**. More specifically, the receptacle **28** is defined by an annular wall portion **46** and a frustoconical wall portion **48**. The annular wall portion **46** defines a cylindrical space having a second diameter. The second diameter is larger than the first diameter of the feeding passage opening **44** at the wall member **38**.

The frustoconical wall portion **48** extends downwardly from the annular wall portion **46**. A larger diameter end of the frustoconical wall portion **48** is adjacent the annular wall portion **46** and the smaller diameter end of the frustoconical wall portion **48** is remote and spaced from the annular wall portion **46**. The size of the smaller diameter end of the frustoconical wall portion **48** is slightly less than the diameter of the feeding passage opening **44** at the wall member **38**, as illustrated in FIG. **1***b*.

The smaller diameter end of the frustoconical wall portion **48** merges with an annular seal member **50** which defines a lower extent of the locking cap member receptacle **28**. The seal member **50** extends into the feeding lumen **16** and defines an opening having a third diameter. The third diameter is the smallest portion of the feeding lumen **16**, with the exception of the anti-reflux valve **26**. The sealing member **50** is located immediately vertically adjacent the anti-reflux valve **26**, (i.e., between the locking cap member **30** which is received within the receptacle **28** and the anti-reflux valve **26**) and cooperates with a feeding adapter **52** to help locate and seal the feeding adapter **52** within the feeding lumen **16**, as will be discussed more fully hereafter.

The anti-reflux valve **26** is integrally formed with the bolster portion **14** in the first preferred embodiment of the present invention illustrated in FIGS. **1***a*–**1***d*. The anti-reflux valve **26** in the preferred and illustrated embodiment is a duck-bill type valve having a plurality of flexible arm members. Preferably, two arm members are provided, each of the arm members integrally extending from the bolster portion relatively beneath the sealing member **50** and at an angle to the longitudinal axis of the tubular member **12**.

The inflation passage **18** curves as it passes through the bolster portion **14** between the inflation valve housing **34** and the tubular member **12**. A generally constant thickness of material is maintained between the inflation passage **18** and the receptacle **28** as the inflation passage curves toward the inflation valve housing **34** to prevent distortion and compression of the inflation passage by forces applied to the cap member **30**, as will be described more fully hereinafter. The inflation passage **18** extends from a base wall **54** of the valve housing **34**, through the bolster portion **14**, and into and through the tubular member **12**.

The inflation valve housing **34** includes a cylindrical wall **56** which extends upwardly parallel to the wall member **38** and laterally in a direction generally opposite or away from the closure member **32**, as illustrated. The base wall **54** of the valve housing **34** is generally perpendicular to the wall member **38**. Relatively beneath the cylindrical wall **56**, the wall member **38** provides a generally planar lower surface which is co-planar with a lower surface of the cap retainer portion **36** radially surrounding the tubular member **12**. As such, the lower surface of the wall member **38** defines a support surface which engages an exterior body surface during use of the feeding device **10**, as will be apparent to one skilled in the art.

The inflation valve housing **34** is adapted to sealingly receive an inflation valve **58**. The inflation valve **58** (shown in dashed lines in FIG. **1***a*) is sealing secured within the inflation valve housing **34** by silicone-based adhesive, or other well known sealing means. The inflation valve **58** preferably includes a check valve plunger **60** which is biased by a spring **62** to a closed position preventing fluid flow out of the balloon member **24**. The plunger **60** is mounted in a plastic valve housing **64** and is manually moved in a longitudinal direction against the spring bias away from a housing-provided seat **66** to an unseated or open position permitting fluid flow therepast. Numerous interchangeable valves of this type are commercially available and known in the art and, therefore, the inflation valve will not be discussed further herein.

The locking cap member **30** is preferably a one-piece molded part, and is illustrated in FIGS. **2***a*–**2***c*. The cap

member **30** includes upper and lower ring-shaped wall members **68**, **70** which are joined by a cylindrical interconnecting wall **72**. The upper wall member **68** includes an annular upper surface which slopes downwardly and outwardly. The lower wall member **70** has a frustoconical outer surface which merges into a short annular vertical surface. As such, the lower wall member **70** has a peripheral shape which generally conforms to the shape of the receptacle **28** formed in the bolster portion **14**, and is designed to be received within the receptacle **28**, as will be defined more fully hereinafter. In this regard it is important to note that the frustoconical outer surface of the lower wall member **70** permits a reduction in the thickness of the bolster portion **16** while maintaining an appropriate thickness between the cap member and the bottom surface of the wall member **38**. The reduced height dimension of the cap member **30** at the lateral sides thereof provided by the angled or frustoconical surface of the lower wall member **70** reduces the lateral height dimensions of the receptacle **28**, and thereby increases the material thickness at these areas. As such, the shape of the cap member **30** permits the feeding device **10** according to the present invention to have a lower profile than would otherwise be possible.

An annular peripheral groove **74** is formed or defined between the upper and lower wall members **68**, **70** and radially outward of the interconnecting wall **72**. The annular groove **74** is shaped and dimensioned to receive the annular rib **45** surrounding the feeding passage opening **44** in the bolster portion **14**. As such, the upper wall member **68** abuts the outer surface **40** of the wall member **38** and overlies and surrounds the feeding lumen opening **44**. The annular rib **45** is trapped between the upper and lower wall members **68**, **70**.

An inner surface of the cap member **30** defines a keyway or locking adapter receptacle **76** into which the feeding adapter **52** can be inserted and removably secured in a push-and-twist-to-lock fashion.

The keyway **76** has a cylindrical main passageway **78** and a generally square slot **80**, as shown best in FIG. **2***b*. A radially inward extending wall **82** defines a bearing or support surface, as will be described hereinafter. A circular recess **84** is formed in the lower wall member **70** relatively beneath the wall **82** coaxial with the passageway **78**, and extends downwardly from the passageway **78**. A radius of the circular recess **84** is approximately equal to a radius of the cylindrical main passageway **78** plus the radial depth of the square slot **80**.

A stop member **86** projects radially inwardly and integrally from the inner surface of the lower wall member **70** and into the circular recess **84**. The stop member **80** projects radially inward from the lower wall member inner surface a distance generally identical to the radial depth of the square slot **80**. The stop member **86** is radially offset relative to the square slot **80** such that the adapter **52**, to be described hereafter, can be inserted into the keyway **76** and turned a predetermined amount before engaging the stop member **86**. As such, the circular recess **84** defines a receptacle in which a portion of the feeding adapter is received and rotatably secured.

When the adapter **52** is inserted into the cap member **30** and rotated such that a key portion **88** of the adapter is radially offset or out of alignment with the square slot **80**, the adapter is vertically retained within the locking cap member **30** by engagement of the key **88** with the wall **82**, and is prevented from being moved axially or longitudinally. In the preferred and illustrated embodiment, the stop member **86** is radially offset, in a clockwise direction, between about 90° to about 180° from the square slot **80**. More preferably, the stop member **86** is radially offset, in a clockwise direction, between about 110° and 130° and, most preferably, is radially offset, in a clockwise direction, from the square slot **80** about 120°, as illustrated.

The feeding adapter **52** shown in FIGS. **3***a*–**3***d*, cooperates with the locking cap member **30** to define a locking means which securely fastens the feeding adapter **52** to the locking cap member **30**. The feeding adapter **52** also cooperates with the sealing member **50** and the anti-reflux valve **26** to seal a lower dispensing portion **90** of the feeding adapter to the feeding device. It should be apparent that various different configurations of feeding adapters could be used with the feeding device according to the present invention. For example, the preferred and illustrated feeding adapter is identified as a 90° adapter, and is preferred due to its low profile which limits the projection of the device from the feeding device which is desirable from an aesthetic and functional viewpoint for the user. Alternative designs, such as ones wherein the adapter extends generally coaxial with the tubular portion of the feeding device, are envisioned.

The preferred feeding adapter **52** includes the lower dispensing portion **90** which extends downwardly from a body member **92**. A connecting portion **94** extends laterally from the body member **92** and generally perpendicular to the dispensing portion **90**. A passage **95** is formed through the feeding adapter from the connector portion **94**, body portion **92**, and the dispensing portion **90**, as illustrated.

The dispensing portion **90** is generally elongated and tubular in shape, but includes the key or tab **88** extending radially therefrom. The dispensing portion **90** also includes a radial or annular groove **96**. The groove **96** is located relatively below the key **88**, as illustrated. A lower terminal end **98** of the dispensing portion **90** is beveled or frustoconical such that the dispensing portion **90** narrows toward the lower end thereof.

The key **88** is adapted to be slidably inserted into the square slot **80** of locking cap member **30** as the dispensing portion **90** is simultaneously inserted through the cylindrical main passageway **78**. When the dispensing portion **90** is fully inserted into the locking cap member **30**, the lower terminal end **98** of the dispensing portion **90** extends into and opens the anti-reflux valve **26** while the radial groove **96** receives the sealing member **50**. As such, after rotation of the feeding adapter **52** to move the key **88** out of alignment with the slot **80** and thereby prevent unintended removal of the feeding adapter **52** from the cap member **30** due to the key **88** engaging the wall **82**, the introduction of fluids through the passage **95** and the feeding passage **16** may commence. The liquids are directly installed into the feeding lumen relatively after or downstream of the anti-reflux valve **26**, and a double seal is provided to prevent undesirable backflow of liquid outwardly through the locking cap member **30** and the bolster portion **16**. The double seal is provided by the sealing engagement between the terminal end **98** of the dispensing portion **90** and the anti-reflux valve **26** and the sealing engagement between the sealing member **50** and the radial groove **96** of the dispensing portion **90**.

A separate anti-reflux valve **26***a* is shown in FIGS. **4***a*–**4***d* and forms a portion of a second embodiment of the present invention. The anti-reflux valve **26***a* is intended to be separately formed and thereafter permanently installed into a feeding device generally as illustrated in FIGS. **1***a*–**1***d*, except as noted hereinafter. The main modification to the previously described feeding device is the fact that the

sealing member **50** and anti-reflux valve are removed or not present in the feeding device according to the second embodiment of the present invention to permit insertion or installation of the anti-reflux valve shown in FIGS. **4***a*–**4***d*. Therefore, as will be apparent from the brief description to follow, the separate anti-reflux valve **26***a* is generally identical from a functional point of view as the previously described sealing member **50** and anti-reflux valve **26**.

The anti-reflux valve **26***a* includes a valve member **100**, a sealing member **50***a*. The sealing member **50***a* is ring-shaped and is sealingly received within the annular groove **96** of the dispensing portion **90** of the feeding adapter **52**. The valve member **100** is engaged and opened by the terminal end **98** of the dispensing portion **90**.

While the preferred embodiments of the present invention have been described herein, it is clear that the present invention is not limited thereto. Rather, the invention is capable of numerous modifications and substitutions of parts without departing form the scope and spirit of the present invention as defined by the claims appended hereto.

What is claimed is:

1. A gastrostomy feeding device comprising a bolster portion, a balloon member, and a tubular member extending between said bolster portion and said balloon member, said tubular member and bolster portion cooperating to define an inflation passage and a feeding passage, said inflation and feeding passages extending through said tubular member generally parallel one another and to a longitudinal axis of said tubular member, said bolster portion comprising an anti-reflux valve, an inflation valve housing, a receptacle, and a feeding port, said inflation valve housing receiving an inflation valve and being in fluid communication with said balloon member via said inflation lumen, said receptacle receiving a locking cap member, said cap member being disposed relatively between said feeding port and said anti-reflux valve, wherein said inflation lumen curves as it extends through said bolster portion from said tubular member toward said inflation valve housing to maintain a generally constant thickness of material between said inflation lumen and said receptacle to reduce distortion of the inflation passage by forces applied to the cap member, and wherein said bolster portion further includes a closure member, said closure member having a first end secured to the bolster portion and a second end including a plug which is received within the cap member.

2. A gastrostomy feeding device according to claim **1**, further comprising a feeding adaptor, wherein said cap member defines a keyway and said feeding adaptor defines a key, said feeding adaptor key being received within and removably locked to said keyway in a twist-and-lock fashion.

3. A gastrostomy device according to claim **1**, wherein said receptacle is provided by a cap retainer portion of said bolster portion, said receptacle being defined by a pair of annular wall surfaces and a radial wall, said radial wall surrounding and corresponding to at least a portion of said cap member.

4. A gastrostomy device according to claim **3**, wherein said radial wall includes an annular wall portion and a frustoconical wall portion, said annular wall portion defining a cylindrical space and said frustoconical wall portion extending downwardly from said annular wall portion.

5. A gastrostomy device according to claim **4**, wherein an annular seal member is disposed relatively beneath said frustoconical wall portion, said seal member defining a lower extent of said receptacle.

6. A gastrostomy device according to claim **5**, wherein said cap retainer portion includes an outer wall, said outer wall being penetrated by an opening, said outer wall defining an upper limit of said receptacle.

7. A gastrostomy device according to claim **6**, wherein said anti-reflux valve is located vertically adjacent said seal member.

8. A gastrostomy device according to claim **7**, wherein said anti-reflux valve is integrally formed with the bolster portion and includes a plurality of flexible arms.

9. A gastrostomy feeding device comprising a bolster portion, a balloon member, and a tubular member extending between said bolster portion and said balloon member, said tubular member and bolster portion cooperating to define an inflation passage and a feeding passage, said inflation and feeding passages extending through said tubular member generally parallel one another and to a longitudinal axis of said tubular member, said bolster portion comprising an anti-reflux valve, an inflation valve housing, a receptacle, and a feeding port, said inflation valve housing receiving an inflation valve and being in fluid communication with said balloon member via said inflation lumen, said receptacle receiving a locking cap member, said cap member being disposed relatively between said feeding port and said anti-reflux valve, wherein the cap member comprises upper and lower ring-shaped wall members that are joined by a cylindrical interconnecting wall, said upper and lower ring-shaped wall members extending radially outward farther than said cylindrical interconnecting wall;

wherein said receptacle is defined at least in part by a radial wall surrounding and corresponding to at least a portion of said cap member, said radial wall including an annular wall portion and a frustoconical wall portion, said annular wall portion defining a cylindrical space and said frustoconical wall portion extending downwardly from said annular wall portion;

wherein said gastrostomy device further comprises an annular seal member disposed relatively beneath said frustoconical wall portion, said seal member defining a lower extent of said receptacle;

wherein said anti-reflux valve is located vertically adjacent said seal member;

wherein said cap retainer portion includes an outer wall, said outer wall being penetrated by an opening, said outer wall defining an upper extent of said receptacle;

wherein said bolster portion further includes a closure member, said closure member having a first end secured to the bolster portion and a second end including a plug which is received within the cap member; and

wherein said gastrostomy feeding device further comprises a feeding adaptor, wherein said cap member defines a keyway and said feeding adaptor defines a key, said feeding adaptor key being received within and removably locked to said keyway in a twist-and-lock fashion.

10. A gastrostomy feeding device comprising a bolster portion, a balloon member, a feeding adaptor, and a tubular member extending between said bolster portion and said balloon member, said tubular member and said bolster portion cooperating to define an inflation passage and a feeding passage, said inflation and feeding passages extending through said tubular member generally parallel one another and to a longitudinal axis of said tubular member, said bolster portion comprising an anti-reflux valve, an inflation valve housing, a receptacle, an annular seal member, and a feeding port, said inflation valve housing receiving an inflation valve and being in fluid communica-

tion with said balloon member via said inflation lumen, said receptacle receiving a locking cap member, said cap member being disposed relatively between said feeding port and said anti-reflux valve, wherein said anti-reflux valve is integrally formed with said bolster portion and comprises a plurality of flexible arm members, and wherein said seal member is disposed relatively between said cap member and said anti-reflux valve, and wherein said cap member defines a keyway and said feeding adaptor comprises a key, said feeding adaptor key being received within and removably locked to said cap member keyway in a twist-and-lock fashion.

11. A gastrostomy feeding device according to claim **10**, wherein said feeding adaptor comprises a dispensing portion which is adapted to extend through said cap member and beyond said anti-reflux valve and into said tubular member, said dispensing portion defining an annular groove which sealing receives said seal member.

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UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 6,019,746
DATED : February 1, 2000
INVENTOR(S) : Picha et al.

It is certified that error appears in the above-indentified patent and that said Letters Patent is hereby corrected as shown below:

On the title page:

Item [56] References Cited, U.S. DOCUMENTS, insert --5,458,583 10/1995 McNeely et al.--.

Column 2, Line 43, delete "2c-3c" and insert --2c-2c--.

Column 2, Line 52, delete "III-III" and insert --3d-3d--.

Signed and Sealed this

Twentieth Day of February, 2001

Attest:

NICHOLAS P. GODICI

Attesting Officer

Acting Director of the United States Patent and Trademark Office